

Vital Statistics Advisory Committee (VSAC) Vital Records Protection Advisory Committee (VRPAC) Joint Meeting Meeting Minutes for Wednesday, March 13, 2013 9:00 AM



ATTENDEES:

Convener: Krista Christian, MBA, Chief, Vital Statistics Unit

Committee Members:

Present: Jonathan Teague, MCRP, Malaika Duran, PhD,

Phone: Emily Putnam-Hornstein, PhD

California Department of Public Health (CDPH) Staff:

Present: Laura Lund M. A., Science Advisor, Julie Turner, Cindy

Tanaka-Fong

CALL TO ORDER: The meeting was called to order at 9:05 AM

A/B. WELCOME/INTRODUCTIONS: Krista announced that this was a public meeting conforming to the Bagley-Keene open meeting act. Members of the public are allowed to attend and welcome to participate at the end of the meeting.

Krista informed everyone that the meeting was being recorded to assist with minute taking. Krista introduced CDPH staff. No members of the public attended the meeting.

Research protocols are available for review on our Department's SharePoint site. Protocols are uploaded up to 3 weeks prior to the VSAC meeting and members were encouraged to download and review them early to avoid issues.

Krista announced this was the last meeting for Julie Turner and Emily Stotlar as they were both retiring at the end of this month.

The 2011 Death Statistical Master File and the 2010 Multiple Cause of Death have been released.

We are still looking for new recruits for the committee. If you know of anyone, please have them contact Krista Christian at (916) 552-9873.

C. APPROVAL OF MINUTES FROM THE PREVIOUS MEETING:

Jonathan Teague motioned to approve the January 9, 2013 meeting minutes. Emily Putnam-Hornstein seconded the motion. All Committee members voted to approve the minutes. There were no oppositions. There was one abstention.

D. VSAC RECOMMENDATIONS FROM THE PREVIOUS MEETING:

Attachment 1, the State Registrar's Response to VSAC Recommendations, is a recap of recommendations from the last meeting.

E. NEW BUSINESS:

Twelve projects were reviewed.

The first project reviewed by the Committee was:

Project Title: "Out-of Hospital Sudden Cardiac Death Records

Review"

Principal Investigator(s): Benjamin Colburn, Electrophysiology

Services, University of California, San Francisco

Project Type: New Project CPHS Approval: Approved Project No.: 12-12-1018

Expiration: February 7, 2014

File(s) Requested: 2007-present Special Run EDRS data (selected

variables)

Requested Identifiers: Name, Certificate Number, SSN, Address

Personal Contact:

Identifiers Released:

History:

VSAC Discussion: Concern was made as it was unclear where the data would be obtained. There was reference made to OSHPD providing EDRS data.

VSAC Recommendation(s): Approve the data request. The committe would like to receive clarification on who they were receiving the data from.

VSAC Motions: Jonathan Teague motioned to recommend approval of the data request with the condition we contact the requestor to get clarification on who would be providing the data. Emily Putnam-Hornstein seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending approval. There were no oppositions. There was one abstention. Motion carried.

The second project reviewed by the Committee was:

Project Title: "Follow-up of Infants Born to Pregnant Women with Confirmed or Probable 2009 H1N1 Influenza with Symptom Onset from April 1 through December 31, 2009"

Principal Investigator(s): Meileen Acosta, MPH, Epidemiologist, Solano County Health and Social Services

Project Type: Continuing Project with Changes to the Protocol

CPHS Approval: Approved

Project No.: 10-10-54 12-09-0698

Expiration December 6, 2013

File(s) Requested: 2010 Birth Statistical Master Files (select variables), 2010 Fetal Death Statistical Master File (select variables)

Requested Identifiers BSMF (Name, Mother's Address), FDSMF (Name)

Personal Contact: No
Identifiers Released: No

History: Previous Data Request

VSAC Discussion: No discussion.

VSAC Recommendation(s): Approve the data request.

VSAC Motions: Emily Putnam-Hornstein motioned to recommend approval of the data request. Jonathan Teague seconded the motion.

VSAC Vote: Committee members voted in favor of recommending approval of the data request. There were no oppositions. There was one abstention. Motion carried.

The third project reviewed by the Committee was:

Project Title: "Investigations of Language Learning and Social Cognition in Infants and Children"

Principal Investigator(s): Michael C. Frank, PhD, Stanford

University Language and Cognition Lab

Project Type: New Project CPHS Approval: Approved Project No.: 12-10-0815

Expiration: December 6, 2013

File(s) Requested: 2011 Birth Statistical Master File (selected variables), 2011 Death Statistical Master File (selected variables)

Requested Identifiers: BSMF and DSMF: Name, Mother's Address

Personal Contact: Yes

Identifiers Released: No

History: New Research Project

VSAC Discussion: No discussion.

VSAC Recommendation(s): Approve the data request.

VSAC Motions: Jonathan Teague motioned to recommend the approval of the data. Emily Putnam-Hornstein seconded the motion.

VSAC Vote: The Committee members all voted in favor of recommending approval of the data request. There were no oppositions. There was one abstention. Motion carried.

The fourth project reviewed by the Committee was:

Project Title: "Development of Statewide Perinatal Quality Improvement Metrics with OSHPD PDD/Birth Certificate Linked Data" Principal Investigator(s): Jeffrey Gould, MD, MPH, Stanford University, California Perinatal Quality Care Collaborative (CPQCC)

Project Type: Continuing Project with Changes to Protocol

CPHS Approval: Approved **Project No:** 12-06-0393 **Expiration:** August 2, 2013

File(s) Requested: 2010 Birth Statistical Master File (select variables

with personal identifiers – linked with OSHPD PDD)

Requested Identifiers: California identifiers only

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

VSAC Discussion: No discussion.

VSAC Recommendation(s): Approve the data request.

VSAC Motions: Jonathan Teague motioned to recommend approval of the data request. Jonathan Teague Emily Putnam-Hornstein seconded the motion.

VSAC Vote: The Committee members voted in favor of recommending approval of the data request. There were no oppositions. There was one abstention. Motion carried.

The fifth project reviewed by the Committee was:

Project Title: "Molecular Markers of Preterm Birth – Maternal and Infant Genetic Contributions to Preterm Birth: the Inflammatory Response"

Principal Investigator(s): Martin Kharrazi, PhD, CDPH Genetic

Disease Screening Program

Project Type: Continuing Project with Changes to Protocol

CPHS Approval: Approved

Project No.: 12-11-0925

Expiration: February 7, 2014

File(s) Requested: No new data requested at this time, requesting to share geocoded data with the University of California (UCLA), a

collaborator on the study

Requested Identifiers: N/A

Personal Contact: No

Identifiers Released: No

History: Previous data request. **VSAC Discussion:** No discussion.

VSAC Recommendation(s): Approve the data request.

VSAC Motions: Emily Putnam-Hornstein motioned approval of the data request. Jonathan Teague seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending approval of the data request. There were no oppositions. There was one abstention. Motion carried.

The sixth project reviewed by the Committee was:

Project Title: "Effect of Agricultural Pesticides on Adverse births Outcomes"

Principal Investigator(s): Ashley e. Larsen, PhD Candidate,

University of California, Santa Barbara

Project Type: New Project **CPHS Approval:** Approved **Project No.:** 12-10-0865

Expiration: December 6, 2013

File(s) Requested: 1997-2011 Birth Statistical Master File (select

variables)

Requested Identifiers: Addresses only

Personal Contact: No

Identifiers Released: No

History: New Research Project.

VSAC Discussion: No discussion.

VSAC Recommendation(s): Approve the data request.

VSAC Motions: Jonathan Teague motioned to recommend the approval of the data request. Emily Putnam-Hornstein seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending approval of the data request. There were no oppositions. There was one abstention. Motion carried.

The seventh project reviewed by the Committee was:

Project Title: "OPTN Deceased Donor Potential Study (DDPS)"
Principal Investigator(s): Karl J. McCleary, PhD, MPH, United

Network for Organ Sharing (UNOS)

Project Type: Continuing Project with Changes to Protocol

CPHS Approval: Approved

Project No.: 12-10-0874 Expiration: February 7, 2014

File(s) Requested: 2010 Death Statistical Master file (select

variables)

Requested Identifiers: Name, Certificate Number, Address,

Mother's Maiden Name

Personal Contact: No

Identifiers Released: No

History: Previous Data Request.

VSAC Discussion: It was noted that they were adding a Private

Investigator and asking for additional data.

VSAC Recommendation(s): No discussion.

VSAC Motions: Emily Putnam-Hornstein Jonathan Teague motioned to review the protocol after we receive CPHS approval. Jonathan Teague seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending approval of the data request. There were no oppositions. There was one abstention. Motion carried.

The eighth project reviewed by the Committee was:

Project Title: "gestational Diabetes in Asian Americans: Predictors,

Problems, and Progression"

Principal Investigator(s): Latha Palaniappan, MD, MS, Palo Alto

Medical Foundation Research Institute

Project Type: New Project

CPHS Approval: Approved

Project No.: 12-08-0677

Expiration: October 4, 2013

File(s) Requested: 2007-2011 Birth Statistical Master File (select

variables)

Requested Identifiers: Name, Mother's Address

Personal Contact: No

Identifiers Released: No

History: New Research Project **VSAC Discussion:** No discussion

VSAC Recommendation(s): Approve the data request.

VSAC Motions: Emily Putham-Hornstein motioned to recommend approval of the data request. Jonathan Teague seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending approval of the data request. There were no oppositions. There was one abstention. Motion carried.

The ninth project reviewed by the Committee was:

Project Title: "Longitudinal Study of Hospital Outcomes for California Children"

Principal Investigator(s): Linda L. Remy, PhD, UCSF Family Health Outcomes Project (FHOP)

Project Type: Continuing Project with Changes to Protocol -

additional data requested

CPHS Approval: Approved

Project No.: 09-06-02

Expiration: April 5, 2013

File(s) Requested: 2010-2011 Birth Statistical Master File (select variables), 2010-2011 Death Statistical Master File (select variables), 2010-2011 Fetal Death Statistical Master File (select variables)

Requested Identifiers: BSMF (Name, Certificate Number, Address), DSMF (Name, Certificate Number, Address, MMN), FDSMF (Name, Certificate Number)

Personal Contact: No

Identifiers Released: No

History: Previous Data Request.

VSAC Discussion: There was concern raised about SSN. According to statute, SSN cannot be given out on the birth files except for child

support purposes. Jonathan informed the Committee they have an OSHPD data application from the requestor. OSHPD is trying to determine how to process the application because they normally don't release data with SSNs on it. The SSN is used to construct the linked birth file. The SSN is converted to a linked number and the data is released as a linked data file.

Laura expressed concern that she could not evaluate it on the specific merits of any particular research project because they wanted to do a lot of things with the data that were not described. The committee, in the past, has approved such applications for the purpose of developing a database, and then required the applicant to come back to the committee to evaluate each use of data as a research project. She recommended a similar approach with this request.

Another concern raised was their contract. It appears that the nature of their contract may have changed over time. Terri commented that they have had several issues surrounding the contract and who is responsible for overseeing the data. In the past, they were representing the State, but the State did not want to sign so they are submitting the application on their own behalf.

Emily commented they discussed in detail their research but in other places, it is much more open in terms of how they would be using the data.

As FHOP is part of Maternal, Child, and Adolescent Health (MCAH) Program, they should be able to get the data from them. If MCAH is not supporting this project as part of FHOP, then it may be outside the parameter and they don't address this in the application.

Laura had two concerns about the application: One concern is the use of SSNs to do linkage; the committee could ask them to describe what they plan to do as part of the linkage process. Second would be to request they provide an application describing a specific research study, for which they can build a database, and describe what they need to do to develop the database for that research study. You would have a specific thing to evaluate from a scientific perspective. Malaika Singleton suggested that we seek clarity from the requestor of what the project is; describe what the specific projects are. Ask them to provide more information about building the database.

VSAC Recommendation(s): The committee agreed to recommend that clarification is sought on the number of projects that may be proposed simultaneously and to get clarification on the description of those projects. They would like to request a resubmittal that describes how they will build the database, including the linkage protocol, and a full description of one or more research projects planning use of the data.

VSAC Motions: Jonathan Teague made a motion recommending we contact the requestor to get clarification on the database and number of projects. The project will be reviewed once we get the issues resolved. Emily seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending contacting the requestor to get more clarification. There were no oppositions. There was one abstention. Motion carried.

The tenth project reviewed by the Committee was:

Project Title: "Persistent Organic Pollutants and Breast Cancer Risk: Chemicals Old and New"

Principal Investigator(s): Peggy Reynolds, PhD, Senior Scientist, Cancer Prevention Institute of California (CPIC)

Project Type: Continuing Project with Changes to Protocol

CPHS Approval: Approved

Project No.: 94-04-11 Expiration: April 4, 2008

File(s) Requested: 2006 980-Byte Birth File (select variables), 2005 Death Statistical Master File (select variables)

Requested Identifiers: Birth File (Personal Identifiers), DSMF

(California identifiers only) **Personal Contact:** Yes

Identifiers Released: No

History: Previous Data Request.

VSAC Discussion: No discussion.

VSAC Recommendation(s): Approve the data request.

VSAC Motions: Jonathan Teague motioned to recommend approval of the data request. Emily Putham-Hornstein seconded the motion.

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VSAC Vote: Committee members all voted in favor of recommending approval of the data request. There were no oppositions. Motion carried.

The eleventh project reviewed by the Committee was:

Project Title: "Stanford Translational Research Integrated Database Environment (STRIDE)"

Principal Investigator(s): Susan Weber, PhD, Director, Informatics Systems Development, Stanford Center for Clinical Informatics

Project Type: New Project CPHS Approval: Approved Project No.: 12-10-0805

Expiration: December 6, 2013

File(s) Requested: 1999-2010 Death Statistical Master File (select

variables)

Requested Identifiers: Name, Certificate Number, SSN, MMN,

Address

Personal Contact: No

Identifiers Released: No

History: New Research Project.

VSAC Discussion: It was the understanding of the committee that the researcher would be building a database and they would decide how they would be releasing the data to researchers who have an IRB protocol.

Laura Lund told the Committee that they are not allowed to rerelease the data that they receive for the Committee as this is specifically identified in statute. They are not considering any specific research project and only doing a data linkage project. In the past, the Committee has approved these kinds of projects, as long as they know they cannot release it and can't use it until it is completed.

Krista read an e-mail from Terri. She recommended that the data be withheld and not released for the purposes stated in the protocol. Stanford proposes to use the data to augment their VHR database for future research projects. She would prefer a data request for research related purposes, if using the data for research is their intent.

The Committee has approved the CMQCC project which is exactly the same; database linkage using real time birth data and DHR from various hospitals.

They are saying they are augmenting the electronic health record data base for future use with many projects, they did not mention a specific project they are doing. This is similar to the Remy protocol.

They intend to use the data for many things. We do not know who will be accessing the data.

Terri felt we needed consistency when we have similar situations for reasons of fairness to requesters.

Emily wanted to know what the Committee's protocol is for an infrastructure project. What is the requirement for the use of the data for different research projects after the product and the infrastructure has been developed.

In the past, the Committee has approved infrastructure products only; required researchers to come back to the Committee. That model has been approved by the Committee.

Various researchers from Stanford University would be request data from the clinical warehouse. Laura said that this would not be allowed by statute as this is one of the gray areas in this application; they cannot rerelease the data. Researchers will have to come back to the Committee and the Department with their own projects. We never had a situation other than Biobank but that is within the department. Allow the researchers at Stanford to house and redistribute the data would be similar to the Biobank model; applicants would have to come through the Committee and the Stanford clilnical warehouse would release in lieu of. We have not done this before.

There is a distinction between CMQCC as it was clearly laid out as a research protocol and infrastructure. They have been building this for a while, as it has been an on-going activity established before the

application and looking to continue support data input by using the DSMF.

Emily wanted to know if they were very explicit with developing this product with the clinical warehouse. Any researcher who wants to use parts of the DSMF would have to come back to the Committee through the State IRB process. Then Stanford can release the deidentified data to them once they have gone through the process.

Laura was not sure that we could get around the statute, and proposed the question to the Committee – if they really want to recommend approval of the model. She urged the Committee to have legal look at this as she was concerned about setting a precedence of having a non-CDPH entity rerelease data. We have approved Biobank, but it is CDPH. This would be the first.

Terri recommended not recommending approval for the use of the data until there is clarity on the various issues brought up.

The requestor would be told that the State Registrar needs to review this closer before a final decision could be made. It would be the decision of the State Registrar to approve or not approve. The legal issue should be taken care of first, and then ask for the additional information.

VSAC Recommendation(s): The Committee agreed to seek clarification with the State Registrar as there were concerns surrounding whether or not State statute allows them to rereuse data and create a product that they would release. They also needed clarification on the destruction of the data and how they would manage that process.

VSAC Motions: Emily Putham-Hornstein motioned to recommend clarification of the State Registrar. Jonathan Teague seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending to seek clarification with the State Registrar. There were no oppositions. Motion carried.

The twelfth project reviewed by the Committee was:

Project Title: "California Late Impact of Phototherapy Study (CLIPS)"

Principal Investigator(s): Andrea Wickremasinghe, MD, University

of California San Francisco

Project Type: Continuing Project with Changes to Protocol

CPHS Approval: Approved

Project No.: 12-08-0692

Expiration: October, 4, 2013

File(s) Requested: 1998-2004 Birth Statistical Master File (select

variables)

Requested Identifiers: California identifiers only

Personal Contact: No

Identifiers Released: No

History: Previous Data Request.

VSAC Discussion: No discussion.

VSAC Recommendation(s): Approve the data request.

VSAC Motions: Jonathan Teague motioned to recommend approval of the data request. Emily Putham-Hornstein seconded the motion.

VSAC Vote: Committee members all voted in favor of recommending approval of the data request. There were no oppositions. There was on abstention. Motion carried.

- **F. ITEMS FOR DISCUSSION:** Krista asked the Committee to refer to Item F, Recap of Data Requests Approved in the Vital Statistics Unit, Attachment 3. Ten data requests that did not require VSAC/VRPAC review were reviewed and approved by the Health Information and Research Section.
- **G. PUBLIC COMMENT:** There were no members of the public attending the meeting.
- **H. AGENDA ITEMS:** Krista asked the Committee if there were any agenda items for the next meeting. There were no agenda items.
- **I. ADDITIONAL DISCUSSION:** Terri thanked everyone for their input.

J. MEETING ADJOURNMENT: Emily Putham-Hornstein motioned to adjourn the meeting. Jonathan Teague seconded the motion. Committee members all voted in favor of adjourning the meeting at 10:20 A.M.